EXHIBIT 1

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JOHN SHERMAN, Plaintiff, v. **JOHNSON & JOHNSON, JOHNSON & JOHNSON SERVICES, INC., MEDICAL DEVICE BUSINESS SERVICES, INC., AND DEPUY SYNTHES SALES, INC.** Defendants.	**SUPERIOR COURT OF NEW JERSEY LAW DIVISION: MIDDLESEX COUNTY** **DOCKET NO.** **CIVIL ACTION** **COMPLAINT, JURY DEMAND, AND DESIGNATION OF TRIAL COUNSEL**

NOW COMES, JOHN SHERMAN, ("Plaintiff"), and sues Defendants JOHNSON & JOHNSON ("Johnson & Johnson"), a New Jersey Corporation, JOHNSON & JOHNSON SERVICES, INC. ("JJS"), a New Jersey Corporation, MEDICAL DEVICE BUSINESS SERVICES, INC. ("MDBS"), an Indiana corporation, and DEPUY SYNTHES SALES, INC. ("DSS"), a Massachusetts corporation, (Johnson & Johnson, JJS, MDBS, and DSS collectively referred to herein as "J&J" or "Defendants") and alleges as follows:

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I. PARTIES

1. At all times relevant hereto, Plaintiff, JOHN SHERMAN, was a resident of Arizona.

2. At all times relevant hereto, Johnson & Johnson is and was a New Jersey Corporation with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. Defendant Johnson & Johnson is the parent company of MDBS, DSS, and JJS.

3. At all times relevant hereto, JJS is and was a New Jersey Corporation with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933, and is the parent company of MDBS and DSS.

4. At all times relevant hereto, MDBS is and was a foreign corporation registered to do business in New Jersey, with its principal place of business listed as 700 Orthopaedic Drive, Warsaw, Indiana 46582. MDBS, was formerly known as DePuy, Inc., DePuy Orthopedics, Inc., and DePuy Orthopaedics, Inc.

5. At all times relevant hereto, DSS is and was a foreign corporation registered to do business in New Jersey with its principal place of business listed as 325 Paramount Drive, Raynham, Massachusetts 02767.

II. JURISDICTION AND VENUE

6. Jurisdiction is proper in the courts of the State of New Jersey because Johnson & Johnson and JJS are citizens of the State of New Jersey, they have submitted to the jurisdiction of New Jersey Courts over similar DePuy metal on metal hip implants[1] and substantial acts have

[1] *See e.g. In Re: Depuy ASR Hip Implants Litigation*, Case No. 293, Master Docket No. BER-L-3971-11 (Bergen County). The product currently litigated is the DePuy Pinnacle metal-on-metal hip replacements system. The Defendants received FDA clearance to market the DePuy ASR based on their claims to the FDA that the DePuy ASR was "substantially equivalent" to the DePuy Pinnacle. *See* Exhibit 1.

occurred within New Jersey to confer jurisdiction on the Defendants. Defendants conduct business in every county in New Jersey and are at home in this state.

7. With respect to the allegations made in this Complaint and the conduct leading to Plaintiff's injuries, the DePuy Defendants and Johnson & Johnson worked in concert with one another, pursuant to a common design, provided substantial assistance and encouragement to the tortious conduct of the others and participated in the tortious conduct related to the DePuy Pinnacle MoM hip replacement system subject to this lawsuit. Where the term "Defendants" is utilized in this lawsuit it is in reference to all Defendants because the parties acted in concern with one another such that they were indecipherable from one another.

8. Johnson & Johnson, directly or through the actions of its subsidiaries, at all pertinent times hereto, participated in developing the product, greenlighted its sale worldwide, held the product out as its own, independently promoted the product, exercised ultimate controlling authority over the product's design and promotion, sold the product and derived revenue from its sale such that it exercised control over the research, development, testing, manufacture, production, marketing, promotion, distribution and/or sale of the product known as the DePuy Pinnacle MoM hip replacement system (hereafter "DePuy Pinnacle" or "Pinnacle").[2]

[2] "J & J's role in Ultamet's design, promotion, and sale demonstrates that J & J significantly contributed to the product's placement into the stream of commerce. On design, the record suggests J & J (a) merged DePuy with another subsidiary that developed Ultamet's precursor Ultima, (b) integrated the design teams, and (c) transferred a helpful patent to DePuy. On marketing and sale, J & J (a) reviewed, edited, and approved DePuy's Pinnacle ads, product brochures, journal articles, public statements, and representations to regulators promoting Pinnacle MoMs; (b) provided substantial funding for certain of DePuy's promotional activities; (c) independently promoted MoMs via a satellite telecast to physicians all over the country, including Texas, and a website, hipreplacement.com, which referred visitors to Texas surgeons and allowed Texas residents to have Ultamet-related information mailed directly to them; (d) referred to the product as its own; (e) granted DePuy "market clearance" to "manufacture, use, and sell" Ultamet worldwide; (f) placed its logo on the packaging of the product as received in Texas; and (g) "monitored" Texas surgeon-consultants promoting Ultamet. Also, DePuy generated considerable revenue for J & J's subsidiary Medical Device & Diagnostic. Finally, although it is neither necessary to nor determinative of the jurisdictional question, we note that both the district court and jury found, under Texas tort law, that J & J was a "seller" of Ultamet. This combination of factors—collectively showing that J & J participated in developing Ultamet, greenlighted its sale worldwide, held the product out as its own, independently promoted the product, exercised ultimate controlling authority over the product's design and promotion, and derived revenue from its sale—is sufficient to show that J &

9. At all relevant times, Defendants either directly, or through their agents, apparent agents, servants or employees sold, distributed and marketed over 150,000 DePuy Pinnacle implants, each with the "Johnson & Johnson" logo on the package, to the public, including within the State of New Jersey. In this marketing, the Defendants made use of the name "Johnson & Johnson" to capitalize on the medical profession's and the public's familiarity with Johnson & Johnson and its products. On marketing materials, logos and letterhead, DePuy refers to itself as "a Johnson & Johnson Company." Defendants derive substantial revenue from Pinnacle products used or implanted in the State of New Jersey. As such, Defendants expected or should have expected that their business activities could or would subject them to legal action over this product both in and outside of the State of New Jersey. In fact, in Johnson & Johnson's 2020 Annual Report to shareholders, Johnson & Johnson confirms financial and legal responsibility for the product liability suits related to the Pinnacle product. [3] Johnson & Johnson has already been held liable (including as a "seller" of the device) for compensatory and punitive damages related to injury stemming from the Pinnacle product by three separate juries in MDL bellwether jury trials.[4]

10. All Defendants were also involved in the business of monitoring and reporting adverse events concerning the Pinnacle hip implant and having a role in the decision process and response of Defendants, if any, related to these adverse events.

J was a link in the stream-of-commerce chain. These factors also distinguish J & J's role from the passive parent-subsidiary relationship that we have held insufficient to support jurisdiction." *In re DePuy Orthopaedics, Inc., Pinnacle Hip Implant Prod. Liab. Litig.*, 888 F.3d 753, 779-80 (5th Cir. 2018)

[3] Johnson & Johnson, *Form 10-K, Annual Report Pursuant to Section 13 of the Securities Exchange Act of 1934, for the fiscal year ended January 3, 2021*, at pp. 84-85, available at: https://johnsonandjohnson.gcs-web.com/static-files/e2a329b4-aeb6-438d-a449-f0e282cf8ee0 (last accessed September 15, 2021) (discussing DePuy Pinnacle and ASR litigation, final resolution of DePuy Pinnacle verdicts, and ongoing potential liability related to said products).

[4] See *In Re: DePuy Orthopaedics, Inc. Pinnacle Hip Implant Products Liability Litigation*, MDL 2244, Case No. 3:11-cv-02800-K (March 17, 2016); *In Re: DePuy Orthopaedics, Inc. Pinnacle Hip Implant Products Liability Litigation*, MDL 2244, Case No. 3:15-cv-03484-K (December 1, 2016); and *In Re: DePuy Orthopaedics, Inc. Pinnacle Hip Implant Products Liability Litigation*, MDL 2244, Case No. 3:15-cv-03489-K (November 16, 2017).

11. Defendants are subject to jurisdiction within the State of New Jersey and this Court because:

- Defendants are engaged in substantial and not isolated business activity within the State of New Jersey, Middlesex County.
- Defendants' Pinnacle implant was designed, manufactured, and/or placed into the stream of commerce in the State of New Jersey by Defendants.
- Defendants maintain an office or agency within the State of New Jersey.
- Upon information and belief, at all relevant times, Defendants committed tortious acts within the State of New Jersey out of which these causes of action arise.

12. At all times relevant hereto, the Defendants developed, manufactured, advertised, promoted, marketed, sold and/or distributed the defective Pinnacle hip implant throughout the United States, including within the State of New Jersey and specifically to Plaintiff's implanting physician or their practice group, or to the hospital where the Pinnacle hip was implanted.

13. Plaintiff has reviewed potential legal claims and causes of action against Defendants and has chosen to only pursue state-law claims. Any reference to any federal agency, regulation or rule is stated solely as background information and does not raise a federal question. Defendants Johnson & Johnson and JJS are both New Jersey corporations and both maintained their principal place of business in New Jersey. Accordingly, this Court may rightfully exercise jurisdiction, and venue is proper.

14. Defendants designed, manufactured, fabricated, marketed, packaged, advertised, and sold the Pinnacle hip implant throughout the world, including in Middlesex County, State of New Jersey.

15. Johnson & Johnson knowingly markets to, and derives income from, patients in the State of New Jersey from the sale of Johnson & Johnson products, including the Pinnacle hip implant.

16. This is an action for damages in excess of Fifteen Thousand Dollars ($15,000.00), exclusive of interest and cost.

III. SUMMARY

17. This is a lawsuit involving defective metal on metal ("MoM") hip replacement system designed, manufactured, promoted, marketed, distributed, sold, serviced, and supported by J&J.

18. The particular system at issue in this case was marketed and sold by J&J as the "DePuy Pinnacle MoM hip replacement system."

19. J&J designed, manufactured and sold the MoM Pinnacle system. J&J also previously designed and manufactured another MoM hip system called the Articular Surface Replacement, or "ASR." Both systems were made with articulating components made of the same or materially similar Cobalt Chrome alloy.

20. The ASR's design was predicated upon the design of the Pinnacle such that J&J claimed that the ASR was "Substantially Equivalent" to the Pinnacle "based upon the similarities in design, material composition, and intended use/indications for use."[5]

21. ASR and Pinnacle systems sold for thousands of dollars, each.

22. ASR and Pinnacle systems sold for a premium over other types of hip replacement systems on account of their MoM articulating components.

23. J&J marketed these systems based upon purportedly significant advantages over other hip replacement systems, including non-MoM systems.

24. Unfortunately, Pinnacle and ASR systems, like all MoM implants, release toxic heavy metals into hip implant recipients' tissue, system, and bloodstream.

[5] *See* Exhibit 1.

25. J&J knew or should have known that the first generation of MoM hip replacements, which were utilized in the 1960s and 1970s, were abandoned due to toxic heavy metal poisoning resulting in tissue and bone death.

26. Two of the main early MoM designs, which were abandoned, were the "McKee-Farrar" MoM hip system and the "Ring" MoM hip system.

27. J&J explicitly predicated the design of its Pinnacle and ASR MoM systems on the first generation of MoM systems, including the McKee-Farrar and Ring systems, claiming that the Pinnacle is "substantially equivalent" to these systems.

28. J&J did not conduct a single pre-market test on either the Pinnacle or the ASR to analyze known clinical risks associated with MoM hip replacements.

29. In 2010, J&J recalled their ASR system because of a "higher than expected revision rate" in those systems.

30. Upon notice of increased revisions with the ASR, J&J began to distinguish the Pinnacle from the ASR. This was done to obfuscate the similarities in clinical risk, avoid the cost of another recall, and to continue to seek profits from the Pinnacle.

31. The Pinnacle system, like the substantially equivalent ASR, results in unreasonably high rates of negative clinical outcomes.

32. These negative clinical outcomes:

- manifest in severe pain and limitations on mobility;
- are progressive in nature such that the impact worsens with time and exposure;
- represent an unreasonable risk of harm to patients;
- results in a higher than expected rate of failure necessitating additional surgeries to replace failed implants;
- lead to injuries which can persist even beyond the removal of the failed implants, and
- can lead to organ failure and death.

33. Despite J&J's claims of advantage, both the Pinnacle and the ASR were defective and unreasonably dangerous for the same reason: the cobalt chrome components released toxic heavy metals leading to a high rate of injury as well as revision (replacement) surgery compared with non-MoM implants.

34. Plaintiff was implanted with the Pinnacle and has suffered substantial injuries and damages due to the defects and unreasonable danger from the system. These injuries were proximately caused by J&J's failure to properly test its MoM implants, including the Pinnacle, as well as J&J's failure to properly warn the public regarding the known dangers of the Pinnacle. Further, these injuries were proximately caused by J&J's fraudulent, intentional, and/or negligent omissions and misrepresentations regarding the clinical risks and benefits of the Pinnacle.

IV. ALLEGATIONS

A. Metal on metal hip replacements were tried *and abandoned* decades ago.

35. In the 1960s and early 1970s, hip replacement manufacturers first began to market MoM hip replacements to surgeons.

36. Unfortunately, these early MoM hip replacements caused a high rate of heavy metal poisoning resulting in tissue death, bone loss, and early failure of the implant.

37. When the metal cup and metal head of these implants rubbed together, they released toxic heavy metal cobalt and chromium debris into the body.

38. The cobalt and chromium debris resulted in patients suffering heavy metal poisoning, causing tissue and bone death.

39. These implants failed early, failed often, and were not as safe or effective as implants utilizing metal-on-plastic components and other alternative designs.

40. As a result of the harm seen in the early generation of MoM hip systems, the

medical community abandoned MoM hip systems in the 1970s.

B. J&J used a loophole to revive metal on metal hip replacements and avoid testing for known dangers.

41. Despite the prior failure of the first generation of MoM hip replacements to perform as intended, J&J nonetheless began designing another generation of MoM hip replacements in the late 1990s and early 2000s.

42. This included both the Pinnacle and, later, the ASR systems.

43. Despite their knowledge that early MoM hip replacements were a failure and resulted in heavy metal poisoning, J&J conducted only limited testing of the Pinnacle and ASR, including no clinical testing, before selling them for surgical implantation into the bodies of patients.

44. To avoid comprehensive testing of either the Pinnacle or the ASR, J&J claimed to United States regulators that these systems should be "grandfathered-in" because they were substantially similar to systems sold prior to May 28, 1976.

45. This loophole required no testing for safety or efficacy.

46. J&J did not conduct any pre-market tests on either the ASR or the Pinnacle systems for safety or efficacy.

C. Premarket testing for safety and efficacy would have revealed the unreasonable risk of heavy metal toxicity.

47. Had J&J conducted testing relevant to the safety and efficacy of MoM implants before the Pinnacle was first released in the early 2000s, J&J would have affirmatively discovered that the Pinnacle system releases high amounts of toxic heavy metals resulting in an unreasonable risk of harm and revision surgeries.

48. J&J relied upon laboratory wear testing designed for plastic components to claim that its MoM Pinnacle produces low metal wear.

49. J&J knew or should have known that such testing does not produce reliable data regarding clinical safety or efficacy for MoM implants.

50. J&J misused clinical data from other hip replacement systems, including non-MoM implants as well as first-generation MoM implants.

51. J&J knew or should have known that clinical data from these other hip replacement systems did not support the safety or efficacy of clinical use of the Pinnacle.

52. J&J knew or should have known that what little laboratory tests they relied upon to market the Pinnacle did not reasonably represent clinical use and therefore did not provide reasonably reliable data for the safety or efficacy of the Pinnacle.

53. J&J knew or should have known that a design based upon the failed first-generation MoM hip systems, and a reliance on testing standards utilized for implants with a plastic articulating surface, would expose patients to an unreasonable risk of harm.

54. Internal documents dating back to 1995 show J&J's knowledge of MoM articulations producing metal wear particles, metal ion release, and poor wear results including scratches creating peaks and valleys on the surfaces of the articulating components.

D. <u>The Pinnacle hip system is unsafe.</u>

55. The Pinnacle system was developed to reconstruct diseased human hip joints suffering from conditions such as osteoarthritis, rheumatoid arthritis, avascular necrosis, and fracture among other degenerative conditions.

56. The natural hip joint connects the femur bone of a patient's leg to the patient's pelvis. The hip joint is like a ball in a socket. The socket portion of the hip is called acetabulum. The femoral head at the top of the femur rotates within the acetabulum.

57. The Pinnacle system is comprised of four components: 1) the metal femoral stem, which is inserted inside the femur, 2) the cobalt chrome metal femoral head (or ball), which connects to the top of the stem, 3) the liner, against and inside of which the head moves; and 4) the metal acetabular cup (socket). The acetabular cup, or socket, is comprised of a titanium metal alloy on its outer shell.

58. The Pinnacle system is available with a choice of liner: plastic, ceramic, or cobalt-chrome metal alloy.

59. The cobalt-chrome metal alloy liner is branded as the "Ultamet" liner. The Pinnacle with an Ultamet liner is a "metal-on- metal" system because both articulating surfaces - the femoral head (ball) and acetabular liner (socket) - are made of cobalt-chromium metal. For the purposes of this complaint, reference to the Pinnacle system, generally, is a reference to the Pinnacle system where it is utilized with a metal liner, such as the "Ultamet."

60. The Pinnacle system is defective because it causes release of toxic heavy metals due to the articulation of two cobalt chrome metal alloy surfaces against each other.

61. Further, the Pinnacle system is defective because the material properties of the femoral head and liner (including size, dimensions, weight, finish, clearance, etc.) result in the connection between the femoral head and the stem to be prone to unreasonably high rates of fretting and corrosion. This process results in damage to the components, release of additional toxic heavy metal particles, trunnionosis, component failure, and the need for surgery to replace the failed components.

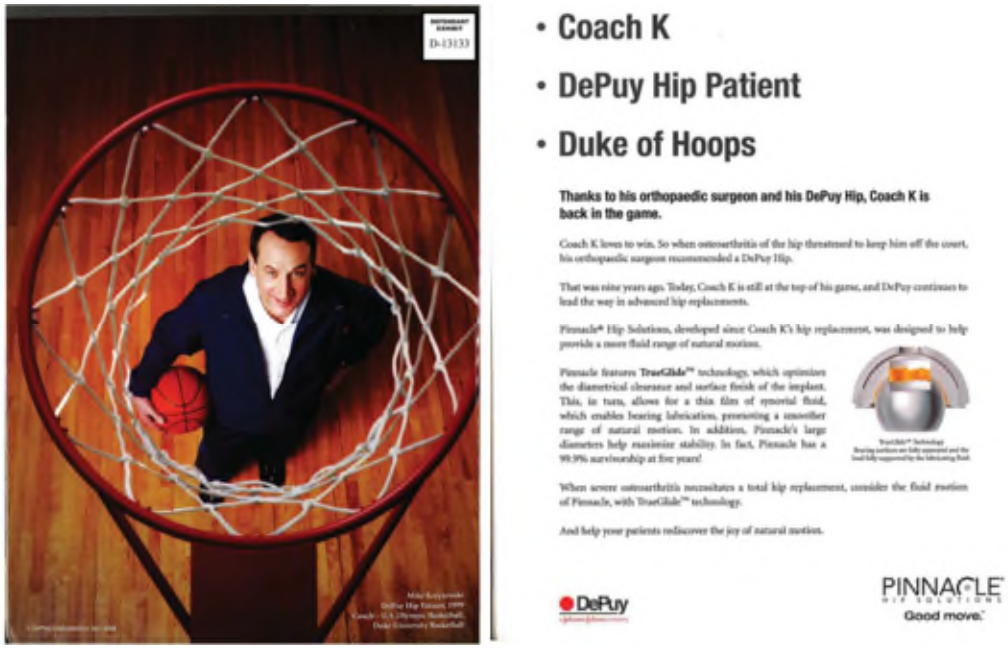
62. The toxicity due to heavy metals is progressive, with greater metal release over time and increasing clinical reaction. Unfortunately, the toxic heavy metals result in severe injury to the hip joint as well as various systemic maladies. Therefore, early intervention to remove the sources of toxicity is crucial. The sooner the Pinnacle system is revised, the less damage is sustained.

63. Clinical outcomes due to heavy metal toxicity from the Pinnacle can include high metal levels, metallosis, pseudotumors, infection, loosening, tissue death, bone death, neurological issues, and many other problems which present with symptoms of pain and loss of function. If the MoM components not removed early enough, the effects can be irreversible and permanent.

E. J&J misrepresented the Pinnacle to sell to more active patients when, in fact, the Pinnacle was even more dangerous for active patients.

64. J&J focused their marketing strategy for the Pinnacle system for use in younger and more active patients in an effort to make the Pinnacle appear safer and more effective for general use and to increase the size of their potential market.

65. For example, J&J touted that the Pinnacle got "Coach K" Mike Krzyewski, coach of the US Olympic Basketball team and the Duke University men's basketball team, "back in the game:"



66. Additionally, J&J's promotional materials show or discuss recipients of the Pinnacle using exercise machines, riding bikes, playing tennis, climbing stairs and otherwise meeting the demands of active patients.

67. J&J knew or should have known that there was no clinical support for their claims of advantage in more active patients.

F. <u>J&J misrepresented the Pinnacle's ability to "lubricate" the moving parts.</u>

68. When two metal objects move against each other, lubrication is critical to minimize wear and the resulting damage to the metal objects.

69. When those two objects are moving inside the human body, and are comprised of toxic heavy metals, the reduction of that wear is more important because it is known to cause injury.

70. J&J touted the Pinnacle's "TruGlide technology" which they claimed "allow[] the body to create a thin film of fluid lubrication between surfaces."

71. J&J claimed that the moving parts are "fully separated" and the load, or weight, is "fully supported by the lubricating fluid."

TrueGlide™ Technology
Bearing surfaces are fully separated and the load fully supported by the lubricating fluid.

72. In essence, J&J claimed that the components were designed in such a way as to allow natural fluids in the hip to adequately lubricate the parts during motion and fully separate the metal components from contact during motion.

73. J&J never tested whether their "TruGlide" technology actually worked in real-world use. For example, J&J's tests involved loading test components into a machine which submerged the components in a lubricant-filled sack and then kept the implants in a narrow range of continuous motion.

74. The tests did not replicate stopping, starting, sitting, standing, stepping up, stepping down, stepping sideways, stepping backward, crouching, tying shoelaces, laying down, or any other typical everyday motion. Each of these motions impacts lubrication and wear differently.

75. J&J knew or should have known that their laboratory tests did not accurately replicate clinical conditions in the human hip joint for a MoM hip system.

76. As a result, J&J knew or should have known that their claims regarding lubrication were untested and made these claims to confuse the medical community into believing that the components would be adequately lubricated in clinical use.

77. J&J's claims regarding lubrication, in fact, were false.

78. The Pinnacle is not adequately lubricated during clinical use and therefore creates excessive wear of toxic heavy metals.

G. J&J misrepresented that the Pinnacle has 99.9% survivorship.

79. J&J claimed that the Pinnacle had a "99.9% midterm survival" rate.

80. "Survival rate" references the percentage of implants which remain implanted and do not need to be removed.

81. Survivorship is material to the medical community's understanding of the safety and efficacy of any hip implant system.

82. J&J is and was aware that Pinnacle system had a higher-than-expected rate of failure and that survivorship with these systems did not reach 99.9% as they claimed.

83. J&J was aware of such a high number of revisions of Pinnacle implants that it rendered impossible their claims of the Pinnacle having a 99.9% midterm survivorship.

84. J&J was also aware that its distributors were not reporting all Pinnacle revision surgeries as was required by J&J policy.

85. J&J was not aware of the true extent of Pinnacle system failures.

86. J&J knew or should have known that their claims of 99.9% survivorship statistic were false.

87. As Pamela Plouhar, PhD., former director of clinical research for Johnson & Johnson, who oversaw the clinical development of the Pinnacle MoM liner, stated during a Pinnacle MoM trial:

> Q. In other words, based on what you know today, the 99.9 percent success rate at five years is false?
> A. It's inaccurate.

Andrews et al, Trial Tr. Vol. 8, 173:8-10, Oct. 17, 2016.

88. J&J nonetheless falsely and deceptively utilized this data point to misrepresent the safety and efficacy of the Pinnacle system.

89. The orthopedic medical community, including Plaintiff's surgeon, relied on this representation as part of their understanding of the safety and efficacy of the Pinnacle which influenced their decision-making process involving use of the Pinnacle.

H. J&J pushed an unproven theory to minimize concern regarding long-term wear.

90. J&J claimed that their MoM implants, both the ASR and Pinnacle, had acceptable long-term wear by citing a theory of "run-in" wear.

91. This theory claims that MoM implants will have higher wear in the short term, and then that wear will taper off and reduce in the long run so that it would not be a clinical concern.

92. This theory claims that the two articulating metal surfaces will "self-polish" as the microscopic peaks of each surface are sheared off during motion, purportedly creating a smoother surface.

93. J&J even marketed an "Asphere" head as a product that would reduce run-in wear.

94. However, J&J did not adequately test either the Pinnacle or the ASR to determine that this theory was correct, even with the Asphere head.

95. In clinical use, the opposite of "run-in wear" is true. Increased time implanted with a MoM hip is associated with increased wear.

96. This is because the metal particles which are sheared off from the peaks become third body particulates inside the joint space. These particulates then create deep scratches in the articulating components. Each of those scratches, in turn, release additional third body particulates.

97. The grinding of the components further serves to grind the third body particulates down into smaller and smaller sized particulates, until they become so small that they can only be measured microscopically. These nano-particles can then become ionic and further toxic.

98. J&J failed to adequately test the Pinnacle to confirm whether the run-in wear theory was applicable to the Pinnacle system.

99. In fact, the theory does not hold true when the Pinnacle is in clinical use.

100. J&J knew or should have known that the run-in wear theory is not applicable to the Pinnacle.

I. When their "Substantially Equivalent" ASR hip system was recalled because of high failure rates, J&J doubled down on selling the Pinnacle instead of investigating and recalling the Pinnacle.

101. Both of J&J's MoM products, the Pinnacle, and the ASR, performed poorly and injured thousands of patients.

102. Likewise, every new MoM implant on the market, regardless of manufacturer, experienced poor clinical results with high numbers of patients exhibiting reactions to the toxic cobalt chrome heavy metals.

103. Almost all these other MoM implants, like the ASR and Pinnacle, had their designs predicated upon the failed first generation of MoM hips.

104. The ASR failed earlier and in higher numbers than any of these already poorly performing implants.

105. In August 2010, J&J recalled more than 93,000 ASR hip implants worldwide, citing "higher than expected" rates of revision.

106. As early as September 2008, researchers connected the failures of the ASR to the "substantially equivalent" Pinnacle.

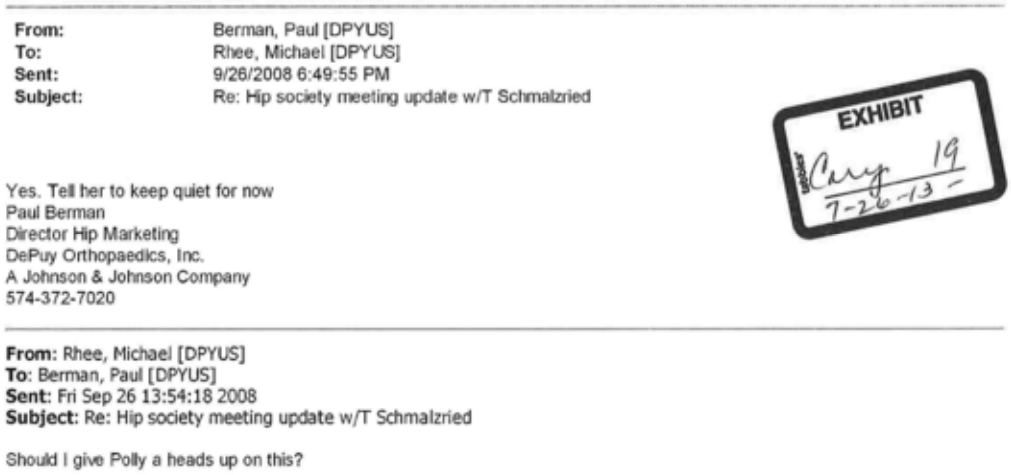
107. A July 2008 investigation into the performance of J&J's implants, including the ASR and Pinnacle hips, completed at the Norfolk & Norwich University Hospital, showed a failure rate of 16% at five years, well beyond acceptable safe standards. Failures often involved corrosion of the femoral stem, metal ion release, fluid collections, tendon rupture, dislocations, and tissue and bone death. Defendants were made aware of such failures but failed to warn patients or surgeons of such failures and failed to recall the Pinnacle.

108. The problems with the Pinnacle system are similar to the issues that gave rise to J&J's recall of the ASR.

109. Like the ASR which was designed by J&J to be "substantially equivalent" to the Pinnacle, the Pinnacle is also prone to early failure, and results in heavy metal toxicity resulting in serious health problems and the need for revision surgery.

110. Internal documents show J&J's initial response to the failure of the ASR was to create a "crises response team" to aid in continuing to sell the Pinnacle notwithstanding the ASR recall.

111. Likewise, when made aware of a discussion of MoM reactions at 2008 hip society meeting, the response from the hip marketing team was to "keep quiet:"



From: Berman, Paul [DPYUS]
To: Rhee, Michael [DPYUS]
Sent: 9/26/2008 6:49:55 PM
Subject: Re: Hip society meeting update w/T Schmalzried

EXHIBIT
Cary 19
7-26-13

Yes. Tell her to keep quiet for now
Paul Berman
Director Hip Marketing
DePuy Orthopaedics, Inc.
A Johnson & Johnson Company
574-372-7020

From: Rhee, Michael [DPYUS]
To: Berman, Paul [DPYUS]
Sent: Fri Sep 26 13:54:18 2008
Subject: Re: Hip society meeting update w/T Schmalzried

Should I give Polly a heads up on this?

6

112. Because of the high costs of the ASR recall, J&J made a calculated decision not to recall the Pinnacle despite the public harm that it has caused and continues to cause.

113. However, J&J did cease to sell the MoM Pinnacle system in 2013, claiming that it was solely due to declining demand for the product and not related to safety.

114. Despite a recall of their other MoM system, the ASR, and knowledge that the Pinnacle represents a similar unreasonable risk of harm to patients, J&J continues to misrepresent the Pinnacle as a high-quality, safe and effective hip replacement product.

V. USE OF THE PRODUCT

115. Plaintiff was implanted with a MoM Pinnacle system on March 4, 2010 at the Banner Desert Medical Center in Mesa, Arizona under the care of surgeon, Larry Sanders, M.D.

116. Over the ensuing years, Plaintiff suffered heavy metal poisoning from the toxic heavy metals released by the Pinnacle System resulting in injury and requiring surgery to remove the defective hip replacements.

[6] Excerpt of Plaintiff's Admitted Exhibit PLT-00062; *see also Alicea* et al, Listing of Exhibits Submitted To The Jury And Demonstrative Exhibits Admitted During Trial, Case 3:15-cv-03489-K, Doc. # 229, Nov. 14, 2017.

117. Plaintiff was forced to undergo surgical removal of the defective Pinnacle system due to heavy metal poisoning on July 8, 2021 at the Abrazo Mesa Hospital in Mesa, Arizona under the care of surgeon, Russell Cohen, M.D.

118. The implanting surgeon's surgical technique was not a cause of Plaintiff's injuries.

119. Plaintiff continues to undergo the slow process of recovery from the surgery that would not have been necessary but for the defective nature of the Pinnacle hip replacement.

120. As a direct and proximate result of the defective Pinnacle hip, Plaintiff was required to undergo surgical removal of the defective system, suffered injury to his muscle and tissue, suffered additional scar tissue formation, and now has a hip replacement with decreased longevity.

121. As a direct and proximate result of the defective Pinnacle hip replacement, Plaintiff suffered injuries, including but not limited to significant pain, injury caused by metallosis, metal wear, metal poisoning, loss of enjoyment of life, and limitation of daily activities.

122. Plaintiff expects to continue suffering such injuries in the future because of the injuries received from the Pinnacle.

123. As a direct and proximate result of the defective Pinnacle, Plaintiff incurred medical expenses and expects to incur additional medical expenses in the future.

124. As a direct and proximate result of the defective Pinnacle, Plaintiff experienced emotional trauma and distress and is likely to experience emotional trauma and distress in the future.

125. The mechanism of failure in Plaintiff's device was a mechanism of failure that Defendants had marketed and warranted would not occur because of the Pinnacle's design and composition. It was also the same failure mechanism that the medical and scientific community had been studying and documenting since the 1960's and 70's, i.e., MoM articulating surfaces

causes metal wear and heavy metal poisoning resulting in tissue death, bone loss, and early failure of the implant.

126. Moreover, the symptoms and findings associated with Pinnacle failures have been reported in the literature are identical to those Plaintiff suffered.

127. As a direct and proximate result of Defendants' defective design, manufacturing, marketing, distribution, sale and warnings of the defective Pinnacle implant, Plaintiff has suffered and continues to suffer both injuries and damages, including, but not limited to: past, present and future physical and mental pain and suffering; physical disability, and past, present, and future medical, hospital, rehabilitative, and pharmaceutical expenses, and other related damages.

VI. CAUSES OF ACTION

FIRST COUNT
VIOLATION OF NEW JERSEY PRODUCTS LIABILITY ACT – FAILURE TO WARN (N.J.S.A. 2A:58C-1, et seq.)

128. Plaintiffs incorporate by reference the allegations in all prior paragraphs and further allege as follows:

129. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce the Pinnacle hip implant; and directly advertised or marketed the product to the FDA, health care professionals, and consumers, including Plaintiff. Therefore, Defendants had a duty to warn of the risks associated with the use of the Pinnacle hip implant.

130. At the time that J&J designed, manufactured, promoted, marketed, sold, supplied, distributed and serviced the Pinnacle hip system implanted in Plaintiff, the Pinnacle contained defects that made it unreasonably dangerous beyond the expectations of the ordinary consumer,

and was unfit for its intended use. The Pinnacle reached Plaintiff without substantial change in the condition in which it was sold.

131. The Pinnacle implant designed, developed, tested, manufactured, distributed, promoted, marketed, and/or sold or otherwise placed into the stream of commerce by Defendants, was in a dangerous and defective condition and posed a threat to any user or consumer.

132. At all material times, Plaintiff was the person the Defendants should have considered to be subject to the harm caused by the defective nature of the Pinnacle implant.

133. The Pinnacle hip was implanted in Plaintiff and used in a manner for which it was intended.

134. This use has resulted in severe physical, financial, emotional and other injuries to Plaintiff as described in this Complaint.

135. Defendants failed to adequately warn health care professionals and the public, including Plaintiff and Plaintiff's implanting physician, of the true risks of the Pinnacle hip implant.

136. Defendants failed to timely and reasonably warn of material facts regarding the safety and efficacy of the Pinnacle implant. Had they done so, proper warnings would have been heeded and no health care professional, including Plaintiff's physician, would have used the Pinnacle hip implant, or no consumer, including Plaintiff, would have purchased and/or consented to the use of the Pinnacle hip implant.

137. Defendants failed to timely and reasonably provide adequate instructions and training concerning safe and effective use of the Pinnacle hip implant.

138. The Pinnacle implant, which Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released into the stream of commerce, was defective due to inadequate post-marketing warnings and/or instruction because Defendants knew or should have known that there was reasonable evidence of an association between MoM hip implants, including the Pinnacle implant, and premature metal wear causing severe adverse local tissue reactions and device failure.

139. Despite knowledge of the United States recall of the substantially equivalent ASR hip system; and having knowledge that the Pinnacle hip system was implanted into Plaintiff, J&J failed to warn Plaintiff of risks associated with the Pinnacle hip system and the risks of allowing the product to remain in Plaintiff's body without medical monitoring.

140. Defendants further failed to provide adequate warnings to health care professionals and the consuming public, including Plaintiff, and continued to aggressively promote the Pinnacle implant.

141. The Pinnacle implant, which Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released into the stream of commerce, was defective due to inadequate post-marketing warnings and/or instruction regarding the increased risk of failure of the Pinnacle implant resulting in revision surgery, although Defendants knew of a safer alternative design including, but not limited to, a metal-on-plastic articulating surface.

142. Defendants failed to perform or otherwise facilitate adequate testing; failed to reveal and/or concealed testing and research data; and selectively and misleadingly revealed and/or analyzed testing and research data.

143. Plaintiff and Plaintiff's physician used the Pinnacle implant for its intended purpose, i.e., total hip replacement.

144. Plaintiff could not have discovered any defect in the Pinnacle implant through the exercise of due care.

145. Defendants, as designers, manufacturers, distributors, promoters, marketers and/or sellers of medical devices are held to the level of knowledge of experts in their field.

146. Neither Plaintiff nor Plaintiff's implanting physician had substantially the same knowledge about the Pinnacle implant as Defendants.

147. Defendants reasonably should have known the Pinnacle implant was unsuited to replace Plaintiff's hip.

148. As a direct and proximate result of Defendants' failure to adequately communicate a warning and/or failure to provide an adequate warning and other wrongful conduct, Plaintiff has sustained and will continue to sustain severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages, as set forth in this Complaint.

149. Defendants are strictly liable in tort to Plaintiff for their wrongful conduct pursuant to the New Jersey Products Liability Act, N.J.S.A. 2A:58C-1 et seq.

150. As a direct and proximate result of the lack of reasonable and adequate instructions or warnings regarding the risks associated with and the defects in the Pinnacle hip system, Plaintiff, suffered damages as set forth in this complaint.

WHEREFORE, Plaintiff respectfully demands judgment against Defendants, JOHNSON & JOHNSON, JOHNSON & JOHNSON SERVICES, INC., MEDICAL DEVICE BUSINESS SERVICES, INC., AND DEPUY SYNTHES SALES, INC., individually, jointly, severally and/or

in the alternative for compensatory and punitive damages, interest thereon, costs of suit and attorney's fee and such other and further relief as the Court deems equitable and just.

SECOND COUNT
VIOLATION OF NEW JERSEY PRODUCTS LIABILITY ACT – DESIGN DEFECT (N.J.S.A. 2A:58C-1, et seq.)

151. Plaintiffs incorporate by reference the allegations in all prior paragraphs and further allege as follows:

152. Defendants had a duty to design and manufacture, distribute, market, promote and sell, the Pinnacle implant so that it was neither defective nor unreasonably dangerous when put to the use for which it was designed, manufactured, distributed, marketed and sold.

153. At the time that J&J designed, manufactured, promoted, marketed, sold, supplied, distributed and/or serviced the Pinnacle hip system implanted in Plaintiff, the Pinnacle contained defects that made it unreasonably dangerous beyond the expectations of the ordinary consumer, and were unfit for their intended use.

154. Defendants expected the Pinnacle hip implant devices they were manufacturing, selling, distributing, supplying, and/or promoting to reach, and they did in fact reach, implanting physicians and consumers in the State of New Jersey and throughout the United States, including Plaintiff and Plaintiff's implanting physician, without substantial change in their condition.

155. At the time the Pinnacle implant left Defendants' possession and the time the Pinnacle implant entered the stream of commerce, it was in an unreasonably dangerous or defective condition. These defects include, but are not limited to the following:

- the Pinnacle implant was not reasonably safe as intended to be used;
- the Pinnacle implant had an inadequate design for the purpose of total hip replacement;
- the Pinnacle implant contained unreasonably dangerous design defects, including a MoM articulating surface;

- the Pinnacle implant is unreasonably dangerous, due to the absence of any lubrication between the head and liner of the hip implant despite Defendant's TruGlide technology representations;
- the Pinnacle implant contained unreasonably dangerous design defects, including the generation of heavy metal ions that cause local and systemic injuries;
- the Pinnacle implant was not appropriately or adequately tested before distribution; and
- the Pinnacle implant had an unreasonably high propensity for device failure which necessitates additional surgery to remove the failed device.

156. At the time and on the occasions in question, the Pinnacle was being properly used for the purpose for which it was intended, and was in fact defective, unsafe and unreasonably dangerous.

157. At the time the Defendants' initial design, manufacture, marketing, and sale of the Pinnacle implant, a feasible, alternative safer design for the Pinnacle implant was known and available, including, but not limited to, a metal-on-plastic articulating surface.

158. At the time subsequent to Defendants' initial design and manufacture and marketing and sale of the Pinnacle implant, including before Plaintiff's hip replacement surgery, Defendants had the ability to eliminate the unsafe character of the Pinnacle implant without impairing its usefulness.

159. The Pinnacle implant, manufactured, supplied, distributed, marketed, promoted and sold by Defendants, were therefore defective in design for formulation in that, when it left Defendants, the foreseeable risk of harm from the product exceeded or outweighed the benefit or utility of the consumer would expect, and/or it failed to comply with federal requirements for these medical devices.

160. As a direct and proximate result of Defendants' wrongful conduct, including the defective and dangerous design and inadequate warnings for the Pinnacle implant, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, economic loss, and other

damages including, but not limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, and pain and suffering, for which Plaintiff is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

161. Defendants are strictly liable in tort to Plaintiff for their wrongful conduct pursuant to the New Jersey Products Liability Act, N.J.S.A. 2A:58C-1 et seq.

162. As a direct and proximate result of the defective and unreasonably dangerous nature of the Pinnacle hip system, Plaintiff, suffered damages as set forth in this complaint.

WHEREFORE, Plaintiff respectfully demands judgment against Defendants, JOHNSON & JOHNSON, JOHNSON & JOHNSON SERVICES, INC., MEDICAL DEVICE BUSINESS SERVICES, INC., AND DEPUY SYNTHES SALES, INC., individually, jointly, severally and/or in the alternative for compensatory and punitive damages, interest thereon, costs of suit and attorney's fee and such other and further relief as the Court deems equitable and just.

THIRD COUNT
VIOLATION OF NEW JERSEY PRODUCTS LIABILITY ACT – MANUFACTURING DEFECT (N.J.S.A. 2A:58C-1, et seq.)

163. Plaintiff incorporates the allegations in all prior paragraphs, and further alleges as follows:

164. The Pinnacle implant Defendants manufactured was defective in construction or composition in that, when it left the hands of Defendants, it deviated in a material way from their manufacturing performance standards and/or it differed from otherwise identical products manufactured to the same design formula. Defendants knew or should have known that the Pinnacle implant could fail early in patients, thereby giving rise to pain and suffering, debilitation and the need for revision surgery to replace the device with the attendant risk of complications and

death from such further surgery, Defendants continued to market the Pinnacle implant as a safe and effective hip implant.

165. J&J was aware that it was unable to adequately conform the manufacturing process to the Pinnacle's design.

166. On information and belief J&J was aware of various "bad lots" produced out of spec and were aware of difficulty machining the product to spec.

167. In violation of N.J. Stat § 2A:58C-1 et. al., the Pinnacle, for the reasons stated herein, were defective and unreasonably dangerous in manufacture.

168. As a direct and proximate result of the defective nature of the Pinnacle hip system, Plaintiff, suffered damages as set forth in this complaint

WHEREFORE, Plaintiff respectfully demands judgment against Defendants, JOHNSON & JOHNSON, JOHNSON & JOHNSON SERVICES, INC., MEDICAL DEVICE BUSINESS SERVICES, INC., AND DEPUY SYNTHES SALES, INC., individually, jointly, severally and/or in the alternative for compensatory and punitive damages, interest thereon, costs of suit and attorney's fee and such other and further relief as the Court deems equitable and just.

FOURTH COUNT
BREACH OF EXPRESS WARRANTY

169. Plaintiff incorporates the allegations in all prior paragraphs, and further alleges as follows:

170. At all relevant times, Defendants manufactured, distributed, advertised, promoted, and sold the Pinnacle hip system.

171. At all relevant times, Defendants intended the Pinnacle hip system be used in the manner that Plaintiff in fact used it and Defendants expressly warranted in its brochures and advertising that each product was safe and fit for use by consumers, that it was of merchantable

quality, that its side effects were minimal and comparable to other hip implant devices, and that it was adequately tested and fit for its intended use.

172. At all relevant times, Defendants were aware that consumers, including Plaintiff, would use the Pinnacle hip system. Therefore, Plaintiff was a foreseeable user of Defendants' Pinnacle hip system.

173. Plaintiff and/or Plaintiff's implanting physician were at all relevant times in privity with Defendants.

174. Defendants' Pinnacle hip system was expected to reach and did in fact reach consumers, including Plaintiff and Plaintiff's implanting physician, without substantial change in the condition in which it was manufactured and sold by Defendants.

175. Defendants breached various express warranties with respect to the Pinnacle hip system, including the following particulars:

- Defendants represented to Plaintiff and Plaintiff's physicians and healthcare providers through their labeling, advertising marketing materials, detail persons, seminar presentations publications, notice letters, and regulatory submissions that the Pinnacle implant was safe and fraudulently withheld and concealed information about substantial risks or serious injury and/or death associated with using the Pinnacle implant;
- Defendants represented to Plaintiff and Plaintiff's physicians and healthcare providers that their Pinnacle implant was as safe, and/or safer than other alternative procedures and devices and fraudulently concealed information, which demonstrated that the Pinnacle implant was not safer than alternatives available on the market; and
- Defendants represented to Plaintiff and Plaintiff's physicians and healthcare providers that the Pinnacle implant was more efficacious than other alternatives and fraudulently concealed information regarding the true efficacy of the Pinnacle implant.

176. In reliance upon Defendants' express warranty, Plaintiff was implanted with Defendants' Pinnacle hip system as prescribed and directed, and therefore, in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

177. At the time of making such express warranties, Defendants knew or should have known that the Pinnacle hip system did not conform to these express representations because the Pinnacle implant was not safe and had numerous serious side effects, many of which Defendants did not accurately warn about, thus making the Pinnacle hip system unreasonably unsafe for its intended purpose.

178. Members of the medical community, including physicians and other healthcare professionals, as well as Plaintiff and the public, relied upon the representations and warranties of Defendants in connection with the use recommendation, description, and/or dispensing of the Pinnacle hip system.

179. Defendants breached their express warranties to Plaintiff in that the Pinnacle hip system was not of merchantable quality, safe, and fit for its intended purpose, nor was it adequately tested.

180. As a direct and proximate result of Defendants' conduct, Plaintiff has sustained and will continue to sustain the damages described herein.

WHEREFORE, Plaintiff respectfully demands judgment against Defendants, JOHNSON & JOHNSON, JOHNSON & JOHNSON SERVICES, INC., MEDICAL DEVICE BUSINESS SERVICES, INC., AND DEPUY SYNTHES SALES, INC., individually, jointly, severally and/or in the alternative for compensatory and punitive damages, interest thereon, costs of suit and attorney's fee and such other and further relief as the Court deems equitable and just.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment and an award of damages against Defendants, as follows:

a. special damages, to include past and future medical and incidental expenses, according to proof;

b. past and future general damages, to include pain and suffering, emotional distress and mental anguish, according to proof;
c. pre-judgment and post-judgment interest;
d. the costs of this action; and
e. treble and/or punitive damages to Plaintiff; and
f. granting any and all such other and further legal and equitable relief as the Court deems necessary, just and proper.

DEMAND FOR JURY TRIAL

Plaintiff respectfully requests that a jury be impaneled to hear this cause of action and to award such damages as the jury finds to be fair and reasonable under the circumstances.

DESIGNATION OF TRIAL COUNSEL

Pursuant to *R.* 4:5-1(c) and *R.* 4:25-4, Plaintiff(s) hereby designates JOSHUA S. KINCANNON, ESQUIRE as trial counsel.

CERTIFICATION PURSUANT TO R. 1:38-7(c)

I hereby certify that confidential personal identifiers have been redacted from documents now submitted to the Court and will be redacted from all documents in the future in accordance with R. 1:38-8(b).

CERTIFICATION PURSUANT TO R. 4:5-1

I hereby certify that the matter in controversy in this action is not the subject of any pending action or arbitration and that no other action or arbitration is presently contemplated.

I certify that the foregoing statements made by me are true. I am aware that if any of the foregoing statements made by me are willfully false, I am subject to punishment.

Dated: June 15, 2022

WILENTZ, GOLDMAN & SPITZER, P.A.
Attorneys for the Plaintiff

By: /s/ Joshua S. Kincannon
JOSHUA S. KINCANNON, ESQUIRE

K040627 (pg 1 of 2)

AUG 5 - 2005

510(k) Summary

NAME OF FIRM:	DePuy Orthopaedics, Inc. PO Box 988 700 Orthopaedics Warsaw, IN 46581-0988
510(k) CONTACT:	Natalie Heck Manager, Regulatory Affairs
TRADE NAME:	DePuy ASR™ Modular Acetabular Cup System
COMMON NAME:	Femoral Hip Prosthesis
CLASSIFICATION:	**Class III per 21 CFR 888.3330 Hip Joint metal/metal semiconstrained, with an uncemented acetabular component prosthesis**
DEVICE PRODUCT CODE:	87 KWA
SUBSTANTIALLY EQUIVALENT DEVICES:	DePuy Pinnacle® Metal-on-Metal Acetabular Cup Line (K002883 & K003523) Wright Medical Metal TRANSCEND® Articulation System (K021349) DePuy Ultima® Unipolar Head and Adapter Sleeves (K965156)

DEVICE DESCRIPTION:

The DePuy ASR™ Modular Acetabular Cup System is comprised of a one-piece metal acetabular cup, a unipolar femoral head, and a taper sleeve adapter.

The acetabular component is designed as a cobalt-chrome molybdenum (CoCrMo) alloy one-piece cup with Porocoat® porous coating and is available in outer diameter sizes 44mm through 62mm in two-millimeter increments. The outer surface of the cup has a porous coating with the addition of a hydroxyapatite (HA) coating. There are no separate liner components to this system, as the liners are integral to the one-piece acetabular cups.

The uni femoral head is manufactured from cobalt-chrome molybdenum (CoCrMo) alloy and is available in a range of diameters from 39 to 55 mm in two-millimeter increments. The uni femoral heads have an internal taper which mates with a taper sleeve adapter specific to DePuy 12/14 or 11/13 tapers. The femoral heads articulate with corresponding one-piece metal acetabular cups.

The taper sleeve adapters are manufactured from cobalt-chrome molybdenum (CoCrMo) alloy. The 12/14 taper sleeve adapters are offered in neck length options of +1.5, +5, and +8.5. The 11/13 taper sleeve adapters were previously cleared in the Ultima® Unipolar Head and Adapter

K040627 (pg 2 of 2)

Sleeves 510(k), K965156 (Jan 24, 1997), and are offered in neck length options of +0, +6, and +12.

INDICATIONS FOR USE:

The DePuy ASR™ Modular Acetabular Cup System is indicated for use in total hip replacement procedures for patients suffering severe pain and disability due to structural damage in the hip joint from rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, collagen disorders, avascular necrosis, and nonunion of femoral fractures. Use of the prosthesis is also indicated for patients with congenital hip dysplasia, slipped capital femoral epiphysis and disability due to previous fusion, where bone stock is inadequate for other reconstruction techniques.

BASIS OF SUBSTANTIAL EQUIVALENCE:

DePuy believes the DePuy ASR™ Modular Acetabular Cup System to be substantially equivalent to the DePuy Pinnacle Metal-on-Metal Acetabular Cup Liners; the Wright Medical Metal TRANSCEND Articulation System; and the DePuy Ultima Adapter Sleeves based upon the similarities in design, material composition, and intended use/indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 5 - 2005

Ms. Natalie Heck
Manager, Regulatory Affairs
DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
PO Box 988
Warsaw, Indiana 46581-0988

Re: K040627
Trade/Device Name: DePuy ASR™ Modular Acetabular Cup System
Regulation Number: 21 CFR 888.3330
Regulation Name: Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis
Regulatory Class: III
Product Code: KWA
Dated: May 23, 2005
Received: May 24, 2005

Dear Ms. Heck:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

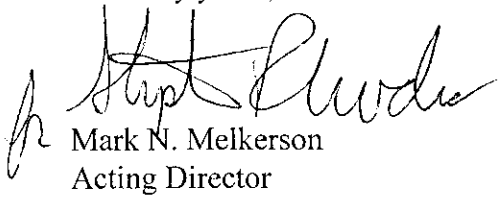
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0210. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K040627
Device Name: DePuy ASR™ Modular Acetabular Cup System

Indications for Use:

The DePuy ASR™ Modular Acetabular Cup System is indicated for use ~~in total~~ hip replacement procedures for patients suffering severe pain and disability due to structural damage in the hip joint from rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, collagen disorders, avascular necrosis, and nonunion of femoral fractures. Use of the prosthesis is also indicated for patients with congenital hip dysplasia, slipped capital femoral epiphysis and disability due to previous fusion, where bone stock is inadequate for other reconstruction techniques.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Posted November 13, 2003)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K040627

Civil Case Information Statement

Case Details: MIDDLESEX | Civil Part Docket# L-002921-22

Case Caption: SHERMAN JOHN VS JOHNSON & JOHNSON
Case Initiation Date: 06/15/2022
Attorney Name: JOSHUA S KINCANNON
Firm Name: WILENTZ GOLDMAN & SPITZER
Address: 90 WOODBRIDGE CENTER DR STE 900 PO BOX 10
WOODBRIDGE NJ 070950958
Phone: 7326368000
Name of Party: PLAINTIFF : Sherman, John
Name of Defendant's Primary Insurance Company (if known): None

Case Type: PRODUCT LIABILITY
Document Type: 1 - 510K Summary
Jury Demand: YES - 12 JURORS
Is this a professional malpractice case? NO
Related cases pending: NO
If yes, list docket numbers:
Do you anticipate adding any parties (arising out of same transaction or occurrence)? NO
Does this case involve claims related to COVID-19? NO

Are sexual abuse claims alleged by: John Sherman? NO

THE INFORMATION PROVIDED ON THIS FORM CANNOT BE INTRODUCED INTO EVIDENCE

CASE CHARACTERISTICS FOR PURPOSES OF DETERMINING IF CASE IS APPROPRIATE FOR MEDIATION

Do parties have a current, past, or recurrent relationship? NO

If yes, is that relationship:

Does the statute governing this case provide for payment of fees by the losing party? NO

Use this space to alert the court to any special case characteristics that may warrant individual management or accelerated disposition:

Do you or your client need any disability accommodations? NO
If yes, please identify the requested accommodation:

Will an interpreter be needed? NO
If yes, for what language:

Please check off each applicable category: Putative Class Action? NO **Title 59?** NO **Consumer Fraud?** NO

I certify that confidential personal identifiers have been redacted from documents now submitted to the court, and will be redacted from all documents submitted in the future in accordance with *Rule* 1:38-7(b)

06/15/2022
Dated

/s/ JOSHUA S KINCANNON
Signed

SUPERIOR COURT OF NEW JERSEY
COUNTY OF MIDDLESEX

JOHN SHERMAN, **Plaintiff(s) – Petitioner(s)**

V. **DOCKET NO.: MID-L-002921-22**

JOHNSON & JOHNSON, ET AL., **Defendant(s) – Respondent(s)**

STATE OF NEW JERSEY
COUNTY OF ESSEX ss.:

Anabela Pinto, the undersigned, being duly sworn, deposes and says that I was at the time of service over the age of 18 years and not a party to this action.

On **6/15/2022** at **11:07 AM**, I served a true copy of a **SUMMONS, COMPLAINT, JURY DEMAND, AND DESIGNATION OF TRIAL COUNSEL, CIVIL CASE INFORMATION STATEMENT** upon **DEPUY SYNTHES SALES, INC. C/O CT CORPORATION SYSTEM** at **820 BEAR TAVERN ROAD, WEST TRENTON, NJ 08628** in the manner indicated below:

Corporation [X] By delivering a true copy of each to **ALEX RHODES** personally.
Deponent knew said corporation served to be the corporation described as the named recipient and knew said individual to be the **INTAKE SPECIALIST** thereof, and an authorized person to accept service of process.

Approximate Description of Receipt	**Female**	**Black**	**Black**	**30**	**5'6"**	**140 lbs**	
	Sex	Skin	Hair Color	Age	Height	Weight	Other

Anabela Pinto
PO BOX 25066
Newark, NJ 07102
800-637-1805

Sworn to before me this
20 day of June, 2022

Notary Public

Alexander Vaye, Esq.
Notary Public
State of New Jersey
New Jersey Attorney ID 008072014

SUPERIOR COURT OF NEW JERSEY
COUNTY OF MIDDLESEX

JOHN SHERMAN, **Plaintiff(s) – Petitioner(s)**

V. **DOCKET NO.: MID-L-002921-22**

JOHNSON & JOHNSON, ET AL., **Defendant(s) – Respondent(s)**

STATE OF NEW JERSEY
COUNTY OF ESSEX ss.:

Anabela Pinto, the undersigned, being duly sworn, deposes and says that I was at the time of service over the age of 18 years and not a party to this action.

On **6/15/2022** at **11:07 AM**, I served a true copy of a **SUMMONS, COMPLAINT, JURY DEMAND, AND DESIGNATION OF TRIAL COUNSEL, CIVIL CASE INFORMATION STATEMENT** upon **MEDICAL DEVICE BUSINESS SERVICES, INC. C/O CT CORPORATION SYSTEM** at **820 BEAR TAVERN ROAD, WEST TRENTON, NJ 08628** in the manner indicated below:

Corporation [X] By delivering a true copy of each to **ALEX RHODES** personally.
Deponent knew said corporation served to be the corporation described as the named recipient and knew said individual to be the **INTAKE SPECIALIST** thereof, and an authorized person to accept service of process.

Approximate Description of Receipt	**Female**	**Black**	**Black**	**30**	**5'6"**	**140 lbs**	
	Sex	Skin	Hair Color	Age	Height	Weight	Other

Anabela Pinto
PO BOX 25066
Newark, NJ 07102
800-637-1805

Sworn to before me this
20 day of June, 20 22

Notary Public

Alexander Vays, Esq.
Notary Public
State of New Jersey
New Jersey Attorney ID 008072014

SUPERIOR COURT OF NEW JERSEY
COUNTY OF MIDDLESEX

JOHN SHERMAN,	**Plaintiff(s) – Petitioner(s)**
AND	**DOCKET.: MID-L-002921-22**
JOHNSON & JOHNSON, ET AL.,	**Defendant(s) – Respondent(s)**

STATE OF NEW JERSEY
COUNTY OF ESSEX ss.:

Daniel Kovach, the undersigned, being duly sworn, deposes and says that I was at the time of service over the age of 18 years and not a party to this action.

On **06/15/2022** at **10:48 AM**, I served a true copy of **SUMMONS, COMPLAINT, JURY DEMAND, AND DESIGNATION OF TRIAL COUNSEL, EXHIBITS** upon **JOHNSON & JOHNSON** at **ONE JOHNSON & JOHNSON PLAZA, NEW BRUNSWICK, NJ 08933** in the manner indicated below:

Electronic Mail [X]	By delivering a true copy of each to **JOHNSON & JOHNSON** electronically on **6/15/2022 at 10:48 AM**, who confirmed receipt via electronic mail on **6/15/2022 at 11:34 AM**. Deponent knew said corporation served to be the corporation described as the named recipient and knew said individual to be the **LAW DEPARTMENT** thereof, and an authorized person to accept service of process.

D. Kovach

Daniel Kovach
PO BOX 25066
Newark, NJ 07102
800-637-1805

Sworn to before me this
20 day of June, 2022

Notary Public

Alexander Vays, Esq.
Notary Public
State of New Jersey
New Jersey Attorney ID 0098072014

SUPERIOR COURT OF NEW JERSEY
COUNTY OF MIDDLESEX

JOHN SHERMAN,	**Plaintiff(s) – Petitioner(s)**
AND	**DOCKET.: MID-L-002921-22**
JOHNSON & JOHNSON, ET AL.,	**Defendant(s) – Respondent(s)**

STATE OF NEW JERSEY
COUNTY OF ESSEX ss.:

Daniel Kovach, the undersigned, being duly sworn, deposes and says that I was at the time of service over the age of 18 years and not a party to this action.

On **06/15/2022** at **10:48 AM**, I served a true copy of **SUMMONS, COMPLAINT, JURY DEMAND, AND DESIGNATION OF TRIAL COUNSEL, EXHIBITS** upon **JOHNSON & JOHNSON SERVICES INC.** at **ONE JOHNSON & JOHNSON PLAZA, NEW BRUNSWICK, NJ 08933** in the manner indicated below:

Electronic Mail [X]	By delivering a true copy of each to **JOHNSON & JOHNSON** electronically on **6/15/2022 at 10:48 AM**, who confirmed receipt via electronic mail on **6/15/2022 at 11:34 AM**. Deponent knew said corporation served to be the corporation described as the named recipient and knew said individual to be the **LAW DEPARTMENT** thereof, and an authorized person to accept service of process.

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